

BC Cancer Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using DOCEtaxel

Protocol Code:

BRAVDOC

Tumour Group:

Breast

Contact Physician:

Dr. Karen Gelmon

ELIGIBILITY:

- First, second, or third line treatment of metastatic breast cancer patients with ECOG performance status 0, 1, or 2, and greater than 3 month life expectancy
- To continue after 8 cycles, a BC Cancer “Compassionate Access Program” request must be approved.

TESTS:

- Baseline: CBC & diff, platelets, [ALT](#), [Alk Phos](#), [LDH](#)
- Before each treatment: CBC & diff, platelets
- Before Cycle 4 and anytime if clinically indicated*: [Bilirubin](#), [Alk Phos](#), [ALT](#), [GGT](#)
*See Precaution #5 for guidelines regarding hepatic dysfunction

PREMEDICATIONS:

- dexamethasone 8 mg PO bid for 3 days, starting one day prior to each DOCEtaxel administration. Patient must receive minimum of 3 doses pre-treatment.
- Additional antiemetics not usually required.
- DOCEtaxel-induced onycholysis and cutaneous toxicity of the hands may be prevented by wearing frozen gloves starting 15 minutes before DOCEtaxel infusion until 15 minutes after end of DOCEtaxel infusion; gloves should be changed after 45 minutes of wearing to ensure they remain cold during the entire DOCEtaxel infusion.

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DOCEtaxel	100 mg/m ²	IV in 250 to 500 mL NS or D5W over 1 hour (see precaution #2) (use non-DEHP equipment)

Repeat every 21 days x 6 cycles. Discontinue if no response after 2 cycles. If patient still receiving benefit after 6 cycles, further 2 cycles may be given.

DOSE MODIFICATIONS:

1. Hematological:

ANC (x 10 ⁹ /L)	Platelets(x 10 ⁹ /L)	Dose	Dose after Neutropenic Sepsis on DOCEtaxel
greater than or equal to 1.5	greater than or equal to 90	100%	75%
1.0 to less than 1.5	70 to less than 90	75%	75%
less than 1.0	less than 70	delay	delay

2. Hepatic dysfunction:

Alkaline Phosphatase		ALT	Dose
less than 2.5 x ULN	and	less than or equal to 1.5 x ULN	100%
2.5 to 5 x ULN	and	1.6 – 6 x ULN	75%
greater than 5 x ULN	or	greater than 5 ULN	discuss with contact physician

ULN = upper limit of normal

PRECAUTIONS:

- 1. Fluid retention:** Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
- 2. Hypersensitivity:** Reactions are common but it is not necessary to routinely initiate the infusion slowly. If slow initiation of infusion is needed, start infusion at 30 mL/h x 5 minutes, then 60 mL/h x 5 minutes, then 120 mL/h x 5 minutes, then complete infusion at 250 mL/h (for 500 mL bag, continue 250 mL/h for 5 minutes and then complete infusion at 500 mL/h). Refer to BC Cancer Hypersensitivity Guidelines.
- 3. Extravasation:** DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.
- 4. Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
- 5. Hepatic Dysfunction:** DOCEtaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST or ALT) may lead to increased toxicity and usually requires a dose reduction. Baseline liver enzymes are recommended before cycle 1 and then if clinically indicated (eg, repeat liver enzymes prior to each treatment if liver enzymes are elevated, liver metastases are present or there is severe toxicity such as neutropenia). If liver enzymes are normal and there is no evidence of liver metastases or severe toxicity, check liver enzymes after 3 cycles (ie, at cycle 4). Note: this information is intended to provide guidance but physicians must use their clinical judgment when making decisions regarding monitoring and dose adjustments.

Call Dr. Karen Gelmon or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

References:

1. Trudeau ME, Eisenhauer ES, Higgins BP, Letendre F et al. Docetaxel in patients with metastatic breast cancer: a phase II study of the National Cancer Institute of Canada – Clinical Trials Group. *J Clin Oncol* 1996;14:422-8.
2. Alexandre J, Bleuzen P, Bonnetterre J, Sutherland W et al. Factors predicting for efficacy and safety of docetaxel in a compassionate-use cohort of 825 heavily pretreated advanced breast cancer patients. *J Clin Oncol* 2000;18:562-end.